

CHARGE: 501 (c)—When shipped, the strength of the *Detoxo* differed from, and its quality fell below, that which it purported and was represented to possess since its labeling represented that the article contained a significant number of viable *Lactobacillus acidophilus* micro-organisms when such was not the case and 502 (a)—the labeling of the articles, when shipped, contained the following false and misleading representations:

(a) That the *Asmar tablets* were an adequate and effective treatment for asthma and allied bronchial conditions, affections of the throat and lungs due to phlegm accumulations in the air passages, spasms of the respiratory system, and conditions requiring respiratory stimulation;

(b) That the *Lipolin* was an adequate and effective treatment for prevention of fatty infiltration of the liver, high blood pressure, hardening of the arteries, liver conditions, capillary fragility, liver damage, cirrhosis of the liver, necrosis of the liver, infective hepatitis, diabetes, multiple sclerosis, alcoholism, psoriasis, gallbladder conditions, and affections of the spleen;

(c) That the *Aratex tablets* were an adequate and effective treatment for arthritis, rheumatism, impaired glandular function, overacid conditions of the body, weakened veins, impure blood, inflammation, fever, nausea, and bursitis;

(d) That the *amino acid wafers* were an adequate and effective treatment for gastrointestinal conditions;

(e) That the *Rectone tablets* were an adequate and effective treatment for piles, impaired glandular function, sluggish liver, inflammation, irritability, bleeding, impaired body functions, and spasms;

(f) That the *herbal diuretic tablets* were an adequate and effective treatment for kidney conditions, bladder conditions, gravel and sediment in the bladder, and pus in the urinary system;

(g) That the *Detoxo* was an adequate and effective treatment for toxemia and affections of the gastrointestinal tract;

(h) That the *Glutamins tablets* were an adequate and effective treatment for epilepsy, nerve exhaustion, melancholy, and mental slowness, and for providing regeneration of nerve tissue, mental uplift, and change of personality.

DISPOSITION: 7-21-55. Default—destruction.

5009. *Rauwolfia serpentina*. (F. D. C. No. 37558. S. No. 6-621 M.)

QUANTITY: 2 100-lb. drums and 1 37-lb. drum of "Pow. *Rauwolfia Serpentina*"; 5 drums containing 750,000 tablets, 22 btl., 1,000 tablets each, 7 btl. 500 tablets each, and 32 btl., 100 tablets each, of "Powdered Whole Root *Rauwolfia Serpentina*" 100-mg. size; and 7 btl., 5,000 tablets each, 16 btl. 1,000 tablets each, 17 btl., 500 tablets each, and 64 btl., 100 tablets each, "Powdered Whole Root *Rauwolfia Serpentina*" 50-mg. size, at Cincinnati, Ohio.

SHIPPED: The powdered *Rauwolfia* was shipped in bulk drums on 9-13-55 from New York, N. Y., by Prentiss Drug and Chemical Co.

LABEL IN PART: (Powder) "Pow. *Rauwolfia Serpentina*"; (tablets) "*Rauwolfia* Brand of Powdered Whole Root *Rauwolfia Serpentina*."

RESULTS OF INVESTIGATION: Upon receipt of the shipment of powdered *Rauwolfia*, the consignee manufactured a portion into tablets. An examination showed that the article contained large amounts of the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina*.

LIBELED: 1-11-55, S. Dist. Ohio.

CHARGE: 501 (d) (2)—the article, when shipped, was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor; 502 (a)—the label designation "Rauwolfia Serpentina" was false and misleading; and 502 (i) (3)—the article was a drug which was not *Rauwolfia serpentina*, and it was offered for sale under the name of another drug, *Rauwolfia serpentina*.

DISPOSITION: 3-23-56. Default—destruction.

5010. Digitalis tablets. (F. D. C. No. 38974. S. No. 42-339 M.)

QUANTITY: 1 fiber drum of 11,425 tablets and 2 fiber drums, each containing 65,000 tablets, at Denver, Colo.

SHIPPED: 2-22-55, from New York, N. Y.

RESULTS OF INVESTIGATION: The tablets were manufactured by the consignee from powdered digitalis leaves, which had been shipped in bulk from New York, N. Y.

Analysis showed that the digitalis potency of the article was less than 85 percent of its declared potency of $1\frac{1}{2}$ grains of U. S. P. digitalis per tablet. The United States Pharmacopeia provides that the potency of digitalis, calculated from the prescribed assay preparation, is satisfactory if the result is not less than 85 percent and not more than 120 percent of the labeled potency.

LIBELED: 3-7-56, Dist. Colo.; libel amended 3-15-56.

CHARGE: 501 (b)—the strength of the article while held for sale differed from the standard set forth in the United States Pharmacopeia for *digitalis tablets*; and 502 (a)—the label statement "Each Tablet Contains: Digitalis, U. S. P. ---- $1\frac{1}{2}$ gr." was false and misleading as applied to an article which contained less than $1\frac{1}{2}$ grains of U. S. P. digitalis per tablet.

DISPOSITION: 5-9-56. Default—destruction.

5011. Befolin No. 1. (F. D. C. No. 38732. S. No. 9-636 M.)

QUANTITY: 12 10-cc. vials at Los Angeles, Calif.

SHIPPED: During 1954, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 33 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-13-55, S. Dist. Calif.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each CC, Contains: Vitamin B-12 Activity From (Beef) Liver Injection U. S. P. Equivalent to Cyanocobalamin 5 Mcg." was false and misleading.

The libel alleged also that another product, Ferro-Calcorbate, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-19-56. Consent—destruction.

5012. Cepevit. (F. D. C. No. 38719. S. No. 9-597 M.)

QUANTITY: 501 30-cc. vials at Los Angeles, Calif.

SHIPPED: 6-30-54, from New York, N. Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 84 percent of the declared amount of vitamin C.